UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

UNITED THERAPEUTICS CORP., Plaintiff, v. SANDOZ, INC., et al., Defendants.	Civil Action Nos. 12-CV-1617 13-CV-316 **MEMORANDUM AND ORDER**

This matter comes before the Court on a motion for summary judgment of invalidity by Sandoz, Inc. ("Sandoz") declaring U.S. Patent No. 7,999,007 ('007 patent) invalid on counts 5 and 6 of both complaints. (12-cv-1216 ECF No. 123 and 13-316 ECF No. 46)

I.

Summary judgment is appropriate under Fed. R. Civ. P. 56(c) when the moving party demonstrates that there is no genuine issue of material fact and the evidence establishes the moving party's entitlement to judgment as a matter of law. *Celotex Corp. v. Catrett*, 477 U.S. 317, 322-23 (1986). A factual dispute is genuine if a reasonable jury could return a verdict for the non-movant, and it is material if, under the substantive law, it would affect the outcome of the suit. *Anderson v. Liberty Lobby, Inc*., 477 U.S. 242, 248 (1986). The Court may grant summary judgment "only when no reasonable jury could return a verdict for the nonmoving party." *Monon Corp. v. Stoughton Trailers, Inc.*, 239 F.3d 1253, 1257 (Fed. Cir. 2001). In considering a motion for summary judgment, the Court must "view the evidence in a light most favorable to the party opposing the motion with doubts resolved in the favor of the opponent." *Ethicon Endo-Surgery, Inc. v. U.S. Surgical Corp.*, 149 F.3d 1309, 1315 (Fed. Cir. 1998); *see*

also Marino, 358 F.3d at 247 (quoting *Anderson*, 477 U.S. at 255) ("In considering a motion for summary judgment, a district court may not make credibility determinations or engage in any weighing of the evidence; instead, the non-moving party's evidence 'is to be believed and all justifiable inferences are to be drawn in his favor.'"). Evidence in support of summary judgment "is viewed through the prism of the evidentiary standard of proof that would pertain at a trial on the merits." *TriMed, Inc. v. Stryker Corp.*, 608 F.3d 1333, 1339-40 (Fed. Cir. 2010) (internal quotations omitted).

Because a patent is presumed valid under 35 U.S.C. § 282, on summary judgment, the party challenging the patent must present undisputed facts that establish the invalidity of the patent by clear and convincing evidence. *Pozen Inc. v. Par Pharm., Inc.*, 696 F.3d 1151, 1165 (Fed. Cir. 2012). Not only does "the patent challenger bear[] the burden of proving the factual elements of invalidity by clear and convincing evidence[,] [t]hat burden of proof never shifts to the patentee to prove validity." *Pfizer, Inc. v. Apotex, Inc*., 480 F.3d 1348, 1359–60 (Fed. Cir. 2007); see also *Symbol Techs., v. Opticon, Inc*., 935 F.2d 1569, 1580 (Fed. Cir. 1991) (describing the burden of proving invalidity by clear and convincing evidence as "a heavy and unshifting burden.") Id. In one hornbook, summary judgment based on an invalidity defense is a high hill to climb because it usually concerns issues of fact, and it "must submit such clear and convincing evidence of invalidity so that no reasonable jury could find otherwise." See, Fed. Judicial Ctr., Anatomy of a Patent Case 108 (2d ed. 2012). Since the Court must view the motion through the "prism of the evidentiary burden the parties would face at trial," disputed facts and the credibility of those witnesses is better determined after hearing the testimony at trial. ." *Id*.

II.

The '007 patent is entitled "Buffer solutions having selective bactericidal activity against gram negative bacteria and methods of using same." The '007 patent specifications explain that "the present invention is directed to the use of buffer systems to maintain a specific pH range as anticidal agents in pharmaceutical preparations." (Col. 3:54-56). More particularly, "the inventors have learned that buffers having high pH (>10) or low pH (<4.5) have bactericidal activity[1] specific for gram negative bacteria and bacteriostatic activity toward gram positive bacteria and other microbes." (Col. 4:16-19) In general terms, the branded product (REMODULIN®), is a treprostinil compound used to treat pulmonary hypertension. Since that compound must be delivered continuously, it is administered intravenously or subcutaneously. The '007 patent (high glycine buffer) is associated with intravenous use only (T. 26, 8-21). The REMODULIN® label instructs that for intravenous use, REMODULIN® must be diluted "with water, saline, or this sterile diluent for FLOLAN® SDF." According to Sandoz, "the sterile diluent for FLOLAN® is a high pH glycine buffer that implicates the '007 patent." (T. 27, 1-3).

In order not to infringe or induce infringement, Sandoz "has carved out any instruction in its label to dilute its product with the sterile diluent for FLOLAN® or any other high pH glycine buffer." (T. 27, 6-9 and T. 29, 13-17). More specifically, Sandoz asserts that its label does not infringe or induce infringement of the high pH glycine buffers because its label initially recommends subcutaneous infusion in which a buffer is not used, and secondly it recommends aseptic techniques when preparing/administering treprostinil (wiping hands with alcohol as opposed to using the FLOLAN® diluent. (T. 37, 1-17)

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[1] Since the lawsuits concern a few different patents, it was difficult to recall the purpose of each patent. Here, the attorneys humorously dubbed the '007 patent with the mnemonic "'007 patent, licensed to kill" due to the reference to the fictional spy James Bond (007) and the bactericidal activity. (T. 26, 3-5).

Plaintiff, United Therapeutics Corp., (UTC) on the other hand, argues that Sandoz is inducing infringement through its instructions because its label uses words and phrases that implicitly instruct to use the FLOLAN® diluent. According to the statute, "whoever actively induces infringement of a patent shall be liable as an infringer." 35 U.S.C. §271(b). As such, the inducement is "a question of affirmative intent." (T. 42, 1-2). Usually, such intent is shown through circumstantial evidence (T. 43, 12-13). UTC argues that Sandoz's label implicitly instructs to use the sterile diluent for FLOLAN®. That is, the label indicates that the intravenous route of a treprostinil injection is associated with those bloodstream infections and that sepsis may be fatal. Accordingly, that language alerts a practitioner to research those bloodstream infections for precautionary measures. (T. 47, 15-18). In fact, the Sandoz label refers to a CDC survey about such infections. (T. 48, 19-2); and the CDC survey easily leads practitioners to review the medical research concerning the CDC survey. One such article found in the research is written by Dr. Rich who recommends using the FLOLAN® diluent to prevent bloodstream infections (T. 52, 3-19). Hence, the label circuitously leads the practitioners to infringe the '007 patent. This argument by UTC presents a fact question as to whether Sandoz is implicitly inducing infringement through deliberate indifference. See, Fed. Judicial Ctr., Patent Law and Practice 185 (7th ed. 2011). In light of the UTC argument, Sandoz's carve out theory has not met the burden of clear and convincing evidence. Therefore, summary judgment is denied.

ORDER

For the reasons set forth above;

IT IS on this 9th day of April, 2014;

ORDERED that the motion for summary judgment by Sandoz, Inc. ("Sandoz") declaring U.S. Patent No. 7,999,007 ('007 patent) invalid on counts 5 and 6 of both complaints (12-cv-1216 ECF No. 123 and 13-316 ECF No. 46) is denied.

s/Peter G. Sheridan
PETER G. SHERIDAN, U.S.D.J.